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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/663,894	09/16/2003	Chi-Ming Che	9661-041-999	4526
32172	7590	01/25/2006	EXAMINER	
DICKSTEIN SHAPIRO MORIN & OSHINSKY LLP 1177 AVENUE OF THE AMERICAS (6TH AVENUE) 41 ST FL. NEW YORK, NY 10036-2714			GEMBEH, SHIRLEY V	
			ART UNIT	PAPER NUMBER
			1614	

DATE MAILED: 01/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/663,894	<b>Applicant(s)</b> CHE, CHI-MING	
	<b>Examiner</b> Shirley V. Gembeh	<b>Art Unit</b> 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-63 is/are pending in the application.  
     4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-63 are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
     a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

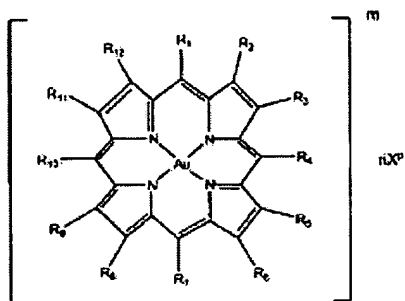
- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____.  |

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***Election/Restrictions***

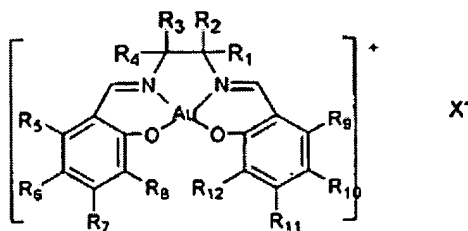
Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-13, 25-37, 55 and 58-59 are, drawn to a method of induction of apoptosis of cancer cells comprising administering a pharmaceutical



composition of \_\_\_\_\_, classified in class 514, subclass 185.

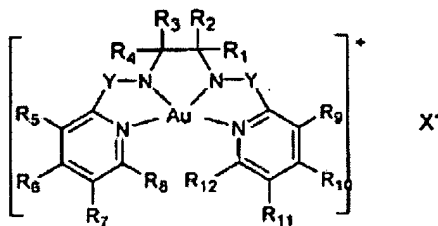
- II. Claims 14-18, 38-42, 56 and 60-61 are, drawn to a method of induction of apoptosis of cancer cells comprising administering a pharmaceutical



composition of \_\_\_\_\_, classified in class 514, subclass 81.

- III. Claim 19-24, 43-48, 57 and 62-63 are, drawn to a method of induction of apoptosis of cancer cells comprising administering a pharmaceutical

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composition of , classified in class  
514, subclass 185.

- IV. Claim 49-50 are, drawn to a pharmaceutical composition, classified in class 514 subclass 185.
- V. Claim 51-52 are, drawn to a pharmaceutical composition classified in class 514 subclass 81.
- VI. Claim 53-54 are, drawn to a pharmaceutical composition classified in class 514 subclass 185.

Inventions of I-III and IV-VI are related as process of making and process of using the product. The use as claimed cannot be practiced with a materially different product. Since the product is not allowable, restriction is proper between said method of making and method of using. The product claim will be examined along with the elected invention (MPEP § 806.05(i)).

Because the inventions are distinct for the reasons given above and the search required for groups I-III, is not necessarily required for groups IV and VI, restriction for examination purposes as indicated is proper. Moreover, because these inventions have acquired a separate status in the art as shown by their different classification, restriction for examination is proper i.e., (the searches are not co-extensive with one another and

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therefore to search both simultaneously would create an undue search burden on the examiner).

The examiner has required restriction between the processes.

Where applicant elects claims that are found allowable, withdrawn methods of the use claims that depend from or otherwise include all the limitations of the allowable claim will be rejoined in accordance with the provisions of MPEP § 821.04. Methods of use claims that depend from or otherwise include all limitations of the patentable claims will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection is governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Specifically, applicant is required to define each of  $R^1$ ,  $R^2$ ,  $R^3$  and  $n$  and any additional variables as required for a particular species.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include

all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

The examiner has required restriction between product and methods of use claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn methods of use claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. Methods of use claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined methods of use claims will be withdrawn, and the rejoined methods of use claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for

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patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and methods of use claims may be maintained. Withdrawn methods of use claims that are not commensurate in scope with an allowed product claim will not be rejoined. See Guidance on Treatment of Product and Process.

Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the methods of use claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

A telephone call was made to Attorney Miller on 1/23/06 to request an oral election to the above restriction requirement and was requested to mail out the restriction/election.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shirley V. Gembeh whose telephone number is 571-272-8504. The examiner can normally be reached on 8:30 -5:00, Monday- Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

*SVS*  
SVG  
1/17/06

  
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SUPERVISORY PATENT EXAMINER  
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